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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,336	03/08/2004	Leone Dall'Asta	12678/5	2011
26646	7590	05/05/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			COVINGTON, RAYMOND K	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/796,336	DALL'ASTA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Raymond Covington	1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-26,28-46 and 48-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26,28-46 and 48-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### ***112 REJECTIONS***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim s 22-26, 28-42 and 44 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

The specification teaches adding terephthalic acid to fuming sulfuric acid to obtain a mixture, which is treated with 1,3,5-trioxane as opposed to the claims, which teach reacting formaldehyde, such as 1,3,5-trioxane, with terephthalic acid, and fuming sulfuric acid. See page 4 of the specification.

Claim s 42-46 and 48-61 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the process steps for the synthesis of citalopram, after synthesis of 5-carboxphthalide, is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 42-46 and 48-61 recites the limitation "synthesis of

citalopram" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim. Claim 22 from which the above claims depend is drawn only to the synthesis of 5-carboxyphthalide with no process steps for the synthesis of citalopram, after synthesis of 5-carboxyphthalide.

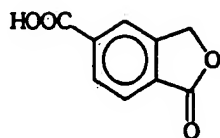
### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26, 28-42 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6458973. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim common subject matter as follows: A process for the preparation of 5-carboxyphthalide of formula



In a reaction by adding formaldehyde and terephthalide acid to fuming sulfuric acid, heating at 120-145° C and isolating 5-carboxyphthalide.

Patentees differ in the use of fuming sulfuric acid containing at least 20% of SO<sub>3</sub> vs. applicants' 25-30%. It is noted that at least 20% includes 25-30%. This is particularly true as all of patentees' examples fall between 25-27%. The use of somewhat different but otherwise analogous process conditions would have been obvious to one of ordinary skill in the art as the results would not have been unexpected. As to the other process parameters note, claims 1-5, 7-23 correspond to applicants' claims 22-26, 28-42 and 44 respectively.

Claims 42-43, 46 and 48-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-67 of U.S. Patent No. 6703516. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim common subject matter as follows: A process for the preparation of citalopram comprising producing 5-carboxyphthalide in a reaction by adding formaldehyde and terephthalide acid to fuming sulfuric acid, heating at 120-145° C and isolating 5-carboxyphthalide.

Patentees differ in the use of fuming sulfuric acid containing at least 20% of SO<sub>3</sub> vs. applicants' 25-30%. It is noted that at least 20% includes 25-30%. This is particularly true as all of patentees' examples fall between 25-27%. The use of somewhat different but otherwise analogous process conditions would have been obvious to one of ordinary skill in the art as the results would not have been unexpected. As to the other process parameters note, claims 1, 20, 21, 8-17, 4 and 40 correspond to applicants' claims 43, 45-61 respectively.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR

only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RKC

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